

CLAIMS

1. (Presently Amended) A pharmaceutical composition comprising (i) 5-[[4-[13-methyl]-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione and a pharmaceutically acceptable salt thereof, and (ii) one or more of a pharmaceutically acceptable carrier or excipient, wherein said mixture has a water content below about 1% (w/w).
2. (Original) The composition of claim 1 in the form of a tablet, a powder or a capsule.
3. (Original) The composition of claim 1, further comprising an antioxidant.
4. (Presently Amended) The composition of claim 3 wherein said antioxidant comprises between 1 and 100 parts by weight and the pharmaceutically acceptable excipient is selected from the group consisting of:
 - between 100 and 400,000 part by weight of anhydrous lactose,
 - between 1 and 100 parts by weight of an antioxidant,
 - between 50 and 500 parts by weight of pregelatinized starch,
 - between 1000 and 10,000 parts by weight of microcrystalline cellulose,
 - between 10 and 500 parts by weight of crospovidone,
 - between 10 and 500 parts by weight of silicon dioxide,
 - between 10 and 500 parts by weight of hydrogenated vegetable oil,
 - between 10 and 500 parts by weight of magnesium stearate,
 - between 10 and 500 parts by weight of hydroxypropyl methylcellulose,
 - between 10 and 500 parts by weight of hydroxypropyl cellulose,
 - between 1000 and 10,000 parts by weight of mannitol,
 - between 10 and 500 parts by weight of stearic acid, or and
 - between 10 and 500 parts by weight of dioxide.
5. (Original) The pharmaceutical composition of claim 1, wherein the water

content is below about 0.5% (w/w).

6. (Original) The pharmaceutical composition of claim 5, wherein the water content is below about 0.1% (w/w).

7. (Original) The pharmaceutical composition of claim 6, wherein the water content is below about 0.05% (w/w).

8. (Presently Amended) The composition of claim 3, wherein the antioxidant is selected from the group consisting of: α -tocopherol, γ -tocopherol, δ -tocopherol, extracts of natural origin rich in tocopherol, L-ascorbic acid and its sodium or calcium salts, ascorbyl palmitate, propyl gallate (PG), octyl gallate, dodecyl gallate, butylated hydroxyl anisole (BHA), and butylated hydroxyl toluene (BHT).

9. (Original) The composition of claim 8, wherein the antioxidant is α -tocopherol.

10. (Original) The pharmaceutical composition of claim 1, further comprising at least one customary additive selected from the group consisting of sweeteners, flavouring agents, colours and lubricants.

11. (Original) The composition of claim 1, further comprising at least one customary additive selected from the group consisting of sweeteners, flavouring agents, colours and lubricants.

12. (Original) The composition of claim 11, wherein the pharmaceutically acceptable excipients are:

between 100 and 400,000 part by weight of anhydrous lactose,
between 1000 and 10,000 parts by weight of microcrystalline cellulose, and
between 01 and 500 parts by weight of magnesium stearate,

expressed in parts by weight per 100 parts of 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiadiazolidine-2,4-dione, or of one of its pharmaceutically acceptable salts.

13. (Original) The composition of claim 12, wherein the amount of talc is 0-10% (weight/weight).

14. (Original) The composition of claim 1, comprising:

5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione potassium salt	9%
cellulose microcrystalline	20%
lactose	66%
magnesium Stearate	0.5%
talc	4.5%

15. (Original) The composition of claim 1, comprising :

5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione potassium salt	18%
cellulose microcrystalline	20%
mannitol	57%
magnesium stearate	0.5%
talc	4.5%

16. (Original) The composition of claim 1, comprising :

5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione potassium salt	18%
lactose	81.5%
magnesium stearate	0.5%

17. (Original) The composition of claim 1, comprising :

5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione potassium salt	0.09%
mannitol	98%
magnesium stearate	02%

18. (Original) The composition of claim 1, comprising:

5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione potassium salt	0.09%
hydrogenated vegetable oil	6.25%
talc	5%
α -tocopherol	50% of 5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione potassium salt
lactose DCL21/mannitol	Up to 200 g.

19. (Original) The composition of claim 1, comprising:

5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione potassium salt	0.09%
providone	7.5%
hydroxypropylmethyl cellulose	1.5%
croscamelose sodium	1.56%
talc	1.1%
magnesium stearate	0.5%
lactose 300 mesh	up to 200 g.

20. (Original) The composition of claim 1, comprising:

5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-2,4-dione potassium salt 0.1096%
mannitol 2.5%
hydroxypropyl- β -cyclodextrin 10 g
and diluted with 92 mL water before use.

21. (Original) The composition of claim 1, comprising :

5-[[4-[3-methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenylmethyl]thiazolidine-

2,4-dione potassium salt 0.1096%

mannitol 2.5%

hydroxypropyl- β -cyclodextrin 10 g

sodium carbonate, anhydrous, 15 mg

Na_2CO_3

and diluted with 92 mL water before use.